OCT 16 2012

Exhibit #2 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K120192

1. Date of Submission: September 25, 2012

2. Sponsor

Weihai Hongyu Nonwoven Fabric Products Co., Ltd.
9-1 Pudong Road, Area of Economy and Technique, Weihai, China, 264205
Establishment Registration Number: 3008489813
Contact Person: Yanfei Liu
Position: Registration Manager
Tel: + (86)-631-3636943
Fax: + (86)-631-3636910
Email: liuyanfei340@163.com

3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 237-023, Shanghai, 200237, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: Disposable Surgical Gowns
Proposed Device Model: M, L, XL, XXL
Classification: II
Product Code: FYA
Regulation Number: 21 CFR 878.4040
Review Panel: General& Plastic Surgery

Intended Use Statement:

Disposable Surgical Gowns, which are blue colored and EO sterilized, are indicated to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. It could achieve Level 3 Barrier Performance as per AAMI PB70:2003. It is for single use only.

5. Predicate Device Identification

Predicate device for Disposable Surgical Gowns
510(k) Number: K100971
Product Name: Hangzhou ATek Medical and Textile Surgical Gowns
Manufacturer: Hangzhou ATek Medical and Textile Co. Ltd.

6. Device Description

Disposable Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Disposable Surgical Gowns are manufactured from three layers nonwoven fabric that is comprised of Spunbond Meltblown Spunbond (SMS) materials. Disposable Surgical Gowns are reinforced with an additional layer of SPP (Syndiotactic Polyprogylene) laminating film in the sleeve and body areas for higher barrier protection.

The proposed Disposable Surgical Gowns include four sizes, which are presented in Table V-1 General Description

Table V-1 General Description of Proposed Device

Proposed Device	Material	Size	Color	Style	Sterility
Disposable Surgical Gowns	SMS	M	Blue	Reinforced	EO Sterilized
		L	Blue	Reinforced	EO Sterilized
		XL	Blue	Reinforced	EO Sterilized
		XXL	Blue	Reinforced	EO Sterilized

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ASTM F2407-06 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities
- AAMI PB70-2003 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities
- AATCC 42-2000 Water Resistance: Impact Penetration Test;
- AATCC 127-2003 Water Resistance: Hydrostatic Pressure Test;
- 16 CFR Part 1610:2008 Standard for the Flammability of Clothing Textiles
- ASTM D 5034 - 09 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ASTM D 5733 - 99 Standard Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure
- ASTM D 1683 - 07 Standard Test Method for Failure in Sewn Seams of Woven Apparel Fabrics
- ISO 9073-10:2003 Textiles - Test Methods for Nonwovens - Part 10: Lint and Other Particles Generation in the Dry State
- ASTM F 1868 - 02 Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate - Part B – Isothermal Evaporative Resistance
- ISO 10993-5:2009: Biological Evaluation of Medical Devices - Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for irritation and skin sensitization
- ISO 11135-1:2007 Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routing control of a sterilization process for medical devices

8. Summary of Comparison

Item	Proposed Device	Predicate Device
Product Code	FYA	FYA
Regulation No.	21 CFR 878.4040	21 CFR 878.4040
Class	II	II
Intended Use	Disposable Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.	Disposable gowns are worn by operating room personnel during surgical procedures to protect both the surgical patient and OR personnel from the transfer of body fluids and particulate material.
Style	Reinforced	Reinforced and Non-reinforced
Size	M, L, XL, XXL	L, XL, XXL
Color	Blue	Unknown
Weight per square	45 g/m^2	Unknown

Thickness		0.16mm	Unknown
Physical Specifications	Resistance to Blood and Liquid Penetration	Level 3 per AAMI PB 70	Level 3 per AAMI PB 70
	Resistance to Tear	≥20 N	≥20 N
	Fire Protection	Class I	s I
	Features for Safe Use	Free of toxic ingredients	Free of toxic ingredients
		the average value of coefficient of variation of linting is 6.2%	Unknown
		Free of Nonfast dyes	Free of Nonfast dyes
Mechanical specifications	Burst strength	≥40 Kpa	≥40 Kpa
	Tensile strength	≥20 N	≥20 N
	Durability	Disposable	Disposable
Performance Testing		Conform to AATCC 42-2000 AATCC 127-2003 16 CFR Part 1610:2008 ASTM D5034 – 09 ASTM D5733 – 99 ASTM D1683 – 07 ISO 9073 Part 10:2003 ASTM F1868 – 02	Conform to AATCC 42-2000 AATCC 127-2003 16 CFR Part 1610:2008 ASTM D5034 – 09 ASTM D5733 – 99 ASTM D1683 – 07 ISO 9073 Part 10:2003 ASTM F1868 – 02
Material		SMS, SPP, Polypropylene, PE, Nylon, Polyester	SMS, Hydro-Entangled (Spunlace), SFT
Biocompatibility		Conform to the requirement of ISO 10993 series Standards	Conform to the requirement of ISO 10993 series Standards
Cytotoxicity		No Cytotoxicity	No Cytotoxicity
Irritation		No intracutaneous reactivity	No intracutaneous reactivity
Sensitization		No delayed dermal contact sensitization	No delayed dermal contact sensitization
Sterilization	SAL	10^{-6}	10^{-6}
	Method	EO Sterilization	EO Sterilization
	Validation	Conforms to ISO 11135	Conforms to ISO 11135
	Package Integrity	Conforms to ISO 11607	Conforms to ISO 11607
	EO Residual	Conforms to ISO 10993-7	Conforms to ISO 10993-7
Label and Labeling		Conforms to FDA Requirements	Conforms to FDA Requirements

9. Substantially Equivalent Conclusion

The proposed devices, Disposable Surgical Gowns, are determined to be Substantially Equivalent (SE) to the predicate device, Hangzhou ATek Medical and Textile Surgical Gowns (K100971), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 16 2012

Weihai Hongyu Nonwoven Fabric Products Company, Limited
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 237-023
Shanghai, 200237 China

Re: K120192
Trade/Device Name: Disposable Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: September 25, 2012
Received: October 1, 2012

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120192
Device Name: Disposable Surgical Gowns
Proposed device model: M, L, XL and XXL

Indications for Use:

Disposable Surgical Gowns, which are blue colored and EO sterilized, are indicated to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. It could achieve Level 3 Barrier Performance as per AAMI PB70:2003. It is for single use only.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie - Williams

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120192